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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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08/981,559 04/13/98 WALLACH

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EXAMINER

HM22/0910

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WASHINGTON DC 20004

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| ART UNIT | PAPER NUMBER |
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DATE MAILED: 1646

09/10/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/981,559

Applicant(s)

Wallach et al.

Examiner

David S. Romeo

Group Art Unit

1646



☒ Responsive to communication(s) filed on 8-23-99

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-34 is/are pending in the application.

Of the above, claim(s) 1-27 and 30-34 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 28 and 29 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-34 are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

1. Applicant's election with traverse of group XLIII, claim 29, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the generic claims share a single inventive concept relating to the modulation of the intracellular domain of TNF and that the examiner has cited no art to establish that the generic claims are not patentable. This is not found persuasive because claims directed to modulatory compounds that "modulate the intracellular domain of TNF" encompass a plurality of disparate, structurally and functionally distinct modulators having the following disparate modulatory activities,

- a. expression,
- b. proteolytic processing,
- c. bioactivity, and
- d. intracellular signaling,
- e. interacting with the intracellular domain, or
- f. interacting with an intracellular effector protein.

Lack of unity is shown because these compounds lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility. Although, the examiner believes that the reasons of record and those above are sufficient to show lack of unity and believes that citation of prior art is not necessary for such a showing in view of

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such reasons, Bluhm et al. (A) disclose compounds that inherently possess one or more of the characteristics of Applicants' modulator claimed in claim 1. See Bluhm et al. (A), Abstract.

Furthermore, claims 25-30 lack unity of invention because binding to the intracellular domain (claims 25-27) is not required for and does not share a special technical feature, based upon a common structural feature, with modulating the cellular activity mediated by the intracellular domain (claims 28 and 29) or the release of said intracellular domain thereof (claim 30).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-27 and 30-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 8.

3. Newly submitted claims 33 and 34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 33 and 34 lack unity of invention because binding to the intracellular domain (claims 33 and 34) is not required for and does not share a special technical feature, based upon a common structural feature, with modulating the cellular activity mediated by the intracellular domain (claims 28 and 29).

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Claims 28 and 29 have been constructively elected by Applicant's election with traverse of group XLIII, claim 29, in Paper No. 8, for prosecution on the merits. Accordingly, claims 33 and 34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### *Claim Objections*

4. Claim 29 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The specification fails to teach "the cellular activity modulated or mediated by the intracellular domain" (claim 28, lines 3-4). Moreover, the specification fails to teach that "modulating the phosphorylation of the intracellular domain" (claim 29, line 2) modulates "the cellular activity modulated or mediated by the intracellular domain" (claim 28, lines 3-4). Accordingly, claim 29 fails to further limit claim 28.

### *Claim Rejections - 35 USC § 112*

5. Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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This rejection is based upon an interpretation of the claims wherein the screening step involves the modulation or mediation of a cellular activity.

The specification fails to teach "the cellular activity modulated or mediated by the intracellular domain" (claim 28, lines 3-4). In the absence of this information the skilled artisan would have to engage in extensive experimentation wherein all conceivable cellular activities are randomly tested for modulation or mediation by the intracellular domain before they could even begin to rationally make and use a screening, identification, characterization, and production process for a molecule that modulates "the cellular activity modulated or mediated by the intracellular domain". Moreover, most physiological activity involves unpredictable factors (*In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)). Furthermore, the specification provides no working examples of "the cellular activity modulated or mediated by the intracellular domain". Moreover, the specification has not taught the skilled artisan how to "produce" a molecule that is identified by the "screening".

In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and use the full scope of the claimed invention.

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6. Claims 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28 and 29 are indefinite because they lack a process step which clearly relates back to the intended use recited in the claim preamble and it is unclear what process is to be used or achieved in the claimed method. It is unclear whether "screening for a molecule capable of modulating" (claim 28, lines 5-6; claim 29, line 4) entails a "modulating" step as part of the screening process (claims 28 and 29, step "a"), or whether the molecule is merely capable of such "modulating" and some other type of screening process is intended. An element that is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. The metes and bounds of the claim(s) are not clearly set forth.

Claims 28 and 29 are further indefinite over the recitation of "capable of modulating" (claim 28, lines 5-6; claim 29, line 4) because it is unclear whether such "modulating" actually occurs as part of the screening process or whether the molecule is merely capable of such "modulating" and some other type of screening process is intended. An element that is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. The metes and bounds of the claim(s) are not clearly set forth.

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Claim 28 is indefinite over the recitation of "the cellular activity modulated or mediated" because the specification fails to teach "the cellular activity modulated or mediated by the intracellular domain" and it is unclear which activity is intended. The metes and bounds of the claim(s) are not clearly set forth.

5           The term "directly or indirectly" in claims 28 and 29 is a relative term which renders the claim indefinite. The term "directly or indirectly" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree of "directness" or "indirectness", and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

10           Claims 28 and 29 provide for the screening, identification, characterization, and production of a molecule, but, since the claim does not set forth any steps involved in the screening, identification, characterization, and production it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a process without any active, positive steps delimiting how this process is actually practiced.

15           Claim 28 is indefinite over the recitation of "modulating" line 12, because that material or functional element that receives or is affected by the action of the "modulating" is unclear. The metes and bounds of the claim(s) are not clearly set forth.



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***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

5 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohta et al.  
(U).

10 This rejection is based upon an interpretation of the claims, wherein an element that is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense.

15 Ohta et al. teach a process comprising screening for LPS (page 2, full paragraph 4 through paragraph bridging pages 2-3; Figure 1), identifying (page 3, full paragraph 1; Figure 3) and characterizing (page 3, full paragraph 1, through page 4, full paragraph 3) said LPS found by said screening, and producing said LPS in substantially isolated and purified form (page 2, full paragraph 3, or Figure 2).

***Conclusion***

9. No claims are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Romeo whose telephone number is (703) 305-4050. The examiner can normally be reached on Monday through Friday from 6:45 a.m. to 3:15 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242.

Faxed draft or informal communications should be directed to the examiner at (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*David Romeo*  
**DAVID ROMEO**  
**PATENT EXAMINER**  
September 9, 1999